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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,953	04/15/2004	Kenneth T. Heruth	1023-363US01	8229

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EXAMINER	
GEDEON, BRIAN T	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/825,953	HERUTH ET AL.	
	Examiner	Art Unit	
	Brian T. Gedeon	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-49* is/are rejected.

7)☒ Claim(s) *17-21,39-43,45 and 49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/16/06, 3/21/06, 9/29/05, 9/26/05, 4/7/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 7, 9, 23, 25, 26, 30, 32, 44, and 47 rejected under 35 U.S.C. 102(e) as being anticipated by Hatlestad et al. (US PG-Pub 2005/0042589 A1).

In regard to claims 1, 24, and 47, Hatlestad et al. describes a sleep quality detection system that detects physiological and non-physiological conditions associated with sleep quality, with means for determine metrics based on the detected conditions associated with sleep and things that disrupt sleep [0022]. The means for detecting and calculating metrics is a processor [0022]. The sleep quality system is coupled to a therapy unit 324 [0071]. Further, Hatlestad et al. teaches that the sleep quality data may provide important information for adjusting therapy [0054]. Figure 3 of Hatlestad et al. shows a cardiac therapy module contained within the system.

In regard to claims 2, 3, 25 and 26, the sleep detection system of Hatlestad et al. has many sensors for monitoring physiological parameters such as patient activity, patient location, posture, heart rate, QT interval, eye movement, respiration rate,

transthoracic impedance, tidal volume, minute ventilation, brain activity, muscle tone, body temperature, time of day, and blood oxygen levels [0081] and [0132]; see Table 1.

In regard to claims 7 and 30, sleep assessment inherently involves a reliable method and device for discriminating between a state of sleep and state of wakefulness [0079] and [0096]. The system of Hatlestad et al. detects sleep arousals [0102].

In regard to claims 9 and 32, the system of Hatlestad et al. acquires data regarding the patient's sleep states or stages, such as REM and NREM, paying attention to the 3 and 4 stages of NREM because that is when most restful sleep occurs.

In regard to claims 23 and 44, the medical device of Hatlestad et al. utilizes implantable components [0055].

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 4-6, 8, 10, 27-29, 31, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatlestad et al. (US PG-Pub 2005/0042589 A1).

In regard to claims 4-6, 8, 10, 27-29, 31, and 33, Hatlestad et al. describes the invention substantially as claimed except for the different sleep quality metrics being determined. Hatlestad et al. acquires sleep quality data during periods of both

wakefulness and sleep [0133] because a more complete picture of sleep quality can then be attained, and charts the trends in disordered breathing, arousal episodes, and other sleep quality aspect, which the Examiner interprets to be forms of "sleep quality metrics" [0022], in order to determine if a therapy should be maintained or adjusted [0054]. Further, Hatlestad et al. teaches that a good indicator of sleep quality is the percentage of time a patient spends in the different sleep stages, which can also give insight into therapy adjustments [0054]. Sleep quality is analyzed in the sleep quality analysis unit 340, figure 3. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to monitor a patient's sleep and wakeful stages in order to calculate a value or metric useful in making a determination in therapy adjustment because knowledge of a patient's sleep patterns during these stages gives a more accurate picture of quality sleep.

5. Claims 11 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatlestad et al. (US PG-Pub 2005/0042589 A1) in view of Remmers et al (US Patent no. 5,645,053).

In regard to claims 11 and 34, Hatlestad et al. substantially describe the invention as claimed except for using a weighting factor to determine the sleep metrics. Remmers et al. teach it is known to use a weighting value with a respiration rate (one of the physiological parameters of the applicant) which results in quicker adaptation of the threshold detection mechanism, col 11 lines 13-17. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and device of Poezevera to include using a weighting factor to determine the sleep

metrics, as taught by Remmers et al, which results in quicker adaptation of the threshold detection mechanism.

6. Claims 12, 13, 35, 36, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatlestad et al. (US PG-Pub 2005/0042589 A1) in view of Poezevera et al. (US Patent no. 6,773,404).

In regard to claims 12 and 35, Hatlestad et al. substantially describes the invention as claimed except the metric value comprising a mean or median sleep quality value. Poezevera et al. describes a system for discriminating between an awake phase and a sleep phase in a patient in an active medical device. The device of Poezevera et al. contains means for computing an average of the successive values of a measured physiological signal. Therefore it would have been obvious to one of ordinary skill in the art to compute average metric values since it helps determine the sleep status of a patient.

In regard to claims 13, 36 and 48, Hatlestad et al. substantially describes the invention as claimed except for comparing a sleep quality metric value to a threshold, and adjusting therapy based on the comparison. Hatlestad et al. does however, teach that knowledge of the patient's sleep patterns may be used to adjust a therapy being delivered to a patient [0054]. Poezevera et al. describes a step, and a means for performing that step, for comparing averaged values of a measured physiological signal with a predetermined threshold to determine the sleep status of a patient. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Hatlestad et al. reference to adjust a therapy for a sleep condition

based on a threshold comparison since Poezevera et al. teaches that a threshold comparison gives insight into a patient's sleep status.

7. Claims 14, 15, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatlestad et al. (US PG-Pub 2005/0042589 A1) in view of Poezevera et al. (US Patent no. 6,773,404) further in view of Park et al. (US Patent no. 6,928,324).

In regard to claims 14 and 37, Hatlestad et al. in view of Poezevera et al. describe the invention as claimed except for the different electrical stimulation adjustments. Park et al. disclose an implantable stimulation device for preventing sleep apnea, in which operating parameters of the device can be modified. Such operating parameters include pulse amplitude, pulse duration, waveshape, electrode polarity, etc, col 13 lines 15-21. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to alter electrical stimulation therapy by altering the parameters above since they are well known in the art as being the general working parameters of electrical stimulation therapy.

In regard to claim 15, Hatlestad et al. in view of Poezevera et al. describe the invention as claimed except for the form of electrical stimulation being neurostimulation. The device of Park et al. can be embodied as an implantable neurostimulator, col 6 lines 45-54. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to improve sleep quality by applying neurostimulation therapy, since it is taught by Park et al., col 6 lines 45-54.

8. Claims 16 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatlestad et al. (US PG-Pub 2005/0042589 A1) in view of Poezevera et al. (US Patent no. 6,773,404) further in view of Gammans (US Patent no. 5,116,852).

In regard to claims 16 and 38, Hatlestad et al. in view of Poezevera et al. describe the invention as claimed except administering a therapeutic agent, and adjusting dosage or infusion rate of said agent. Gammans teaches that application of certain antidepressants may alleviate sleep disorders, thereby improving sleep quality. In view of teaching of Gammans, it would have been obvious to one of ordinary skill in the art at the time the invention was made to improve sleep quality using pharmaceutical agents, and it would have been obvious to adjust dosage or infusion rates base on certain criteria since it has been held that those parameters are the general workable parameters regarding pharmaceutical administration.

9. Claims 22 and 46, are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatlestad et al. (US PG-Pub 2005/0042589 A1) in view of Poezevera et al. (US Patent no. 6,773,404) further in view of Civelli et al. (US Patent no. 6,884,596).

In regard to claims 22 and 46, Hatlestad et al. substantially describes the invention as claimed except treatment of chronic pain. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to treat chronic pain as a method to improve sleep quality since it is taught by Civelli et al. that chronic pain is known to reduce sleep quality, col 7 lines 37-41.

Allowable Subject Matter

10. Claims 17-21, 39-43, 45, and 49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claim 1-49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5-10, 12-23, 25-29, 32-58, 60-66, and 68 of copending Application No. 10/825,955; and over claims 1-11, 12, 14,16-18,19-30, 32-44, 46-50, 52-57, 59-60, 62, 67 and 68 of copending Application No. 10/825,964; and over claims 1, 3-8, 11-16, 19-24, 26-30, 34-36, 38, 39, 41, 44-48, and 69-76 of copending Application no. 10/825,965; and over claims 1-11, 16-34, 38-47, 48,

69, 70, 73-79, 83, 84, 87-92 and 96-99 of copending Application No. 10/826,925; and over claims 1, 3, 8, 9, and 13-15 of copending Application No. 11/081,811; and over claims 1-7, 25, and 28-37 of copending Application No. 11/081,873.

Although the conflicting claims are not identical, they are not patentably distinct from each other because all applications claim an implantable medical device for determining a set of sleep quality metrics.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Rezai et al. (US PG-Pub 2005/0177192)

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272 3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272 6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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BTG